REMARKS

Restriction/Election

The Examiner alleged that claims 5 and 9 are withdrawn from further consideration pursuant to 37 CFR1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on October 9, 2007.

The restriction was made based on the allegation that the protein complex recited in claim 1 was shown in Ikeda et al. However, as discussed below, the protein complex recited in claim 1 is not shown in Ikeda et al. Therefore, claim 1 and claim 5 satisfy the combination of categories provided at 37 CFR 1.475(b).

Claim 9 has been amended to become directed to "an isolated protein complex," the same as claim 1.

Thus, all claims satisfy the unity of invention.

Objection to Specification

The title of the invention was objected to because it allegedly was not descriptive.

Accordingly, the title has been amended to overcome the objection.

Claim Objection

Claim 2 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Accordingly claim 2 has been cancelled. Thus, the rejection has become moot.

Rejections under 35 USC §101

Claims 1-4 were rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-4 have been amended to recite "isolated protein complex" to overcome the rejection.

Rejections under 35 USC §112, Second Paragraph

Claim 2 was rejected under 35 USC §112, second paragraph, as being indefinite.

The Examiner alleged that claim 2 was indefinite because more than one CPV VP3 polypeptide was known at the time of the invention.

Claim 2 has been cancelled. Thus, the rejection has become moot.

Rejections under 35 USC §112, First Paragraph

Claims 1-4 and 6-8 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Claims 1-4 and 6-8 also were rejected under 35 USC §112, first paragraph, because the specification allegedly does not

reasonably provide enablement for all protein complexes as broadly encompassed by the claims.

Claim 1 has been amended as follows:

> An isolated protein complex comprising:
> a polyhedral protein having an insect virus encapsulated therein; and
> a target protein having a restricted region of a capsid protein VP3 of cytoplasmic polyhedrosis virus as an embedding signal for polyhedron,
> wherein the restricted region of capsid protein VP3 is a region from the 41st amino acid residue to the 79th amino acid residue.

Amended claim 1 makes it clear that the restricted region of capsid protein VP3 is a region from the 41st amino acid residue to the 79th amino acid residue.

There is a preceding invention of the present inventor, which relates to a protein complex contributing to protection, preservation and improvement in stability of a target protein and a process for producing the same (D1: WO 02/36785A1). The object of the D1 invention is to embed a polymeric target protein in this polyhedron and to enhance the embedding efficiency. Therefore, by shortening a gene encoding a capsid protein of cytoplasmic polyhedrosis virus, the size (molecular weight) of a protein which can be embedded in a polyhedron is made large, and this target protein is further more efficiently embedded in the polyhedron. Moreover, in the method, the amino acid sequence of VP3, which is a constituent protein of the envelope of cytoplasmic polyhedrosis virus, is introduced to the N-terminus or the C-terminus of the target protein, and this fusion protein is expressed with a baculovirus vector. Here, by infecting an insect cell together with a virus expressing a polyhedral protein of cytoplasmic polyhedrosis virus, the fusion protein is embedded in a polyhedron. Accordingly, it is necessary to fuse a

cDNA encoding a constituent protein of cytoplasmic polyhedrosis virus and a gene encoding a target protein so that a foreign protein expressed with a baculovirus vector, namely, a target protein is inserted at the N-terminus or the C-terminus of the constituent protein of cytoplasmic polyhedrosis virus. At this time, it is important that the open reading frames encoding the constituent protein and the protein of the target protein gene are cloned in-frame. In this way, a recombinant baculovirus expressing the constituent protein of cytoplasmic polyhedrosis virus and the target protein as one fusion protein is constructed, which is described in the above-mentioned invention.

The present invention further improves the above-mentioned invention and it identifies VP3, which is used as an embedding signal for polyhedron, within the specific area. Fig. 5 shows the results obtained by introducing the region from the 39th amino acid residue to the 79th amino acid residue of VP3 into the N-terminus of Cyclin-dependent kinase 5 as a signal for encapsulation in a polyhedron, thereby encapsulating this protein in a polyhedron, and attaching the polyhedron to a slide glass and performing an antigen-antibody reaction on the surface of the polyhedron.

As explained above, because amended claim 1 makes it clear that the restricted region of capsid protein VP3 is a region from the 41st amino acid residue to the 79th amino acid residue, claims 1-4 and 6-8 satisfy the description requirement and the enablement requirement.

Double Patenting

Claims 1-4, 7 and 8 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 18 of co-pending U.S. Patent Application No. 10/415,096, which corresponds to Ohta et al. (WO 02/36785) as cited below.

As the Examiner noted WO 02/36785 corresponds to Ohta et al. cited below. The present invention patentably distinguishes over Ohta et al., as well as WO 02/36785, as discussed below regarding the rejection under 35 USC §102(b) and §103(a).

Rejections under 35 USC §102/103

Claims 1-4 were rejected under 35 USC §102(b) as being anticipated by or, in the alternative, under 35 USC §103(a) as being obvious over Ohta et al. (WO 02/36785; cited in the IDS filed on July 8, 2005).

Claim 1 has been amended to recite "wherein the restricted region of capsid protein VP3 is a region from the 41st amino acid residue to the 79th amino acid residue."

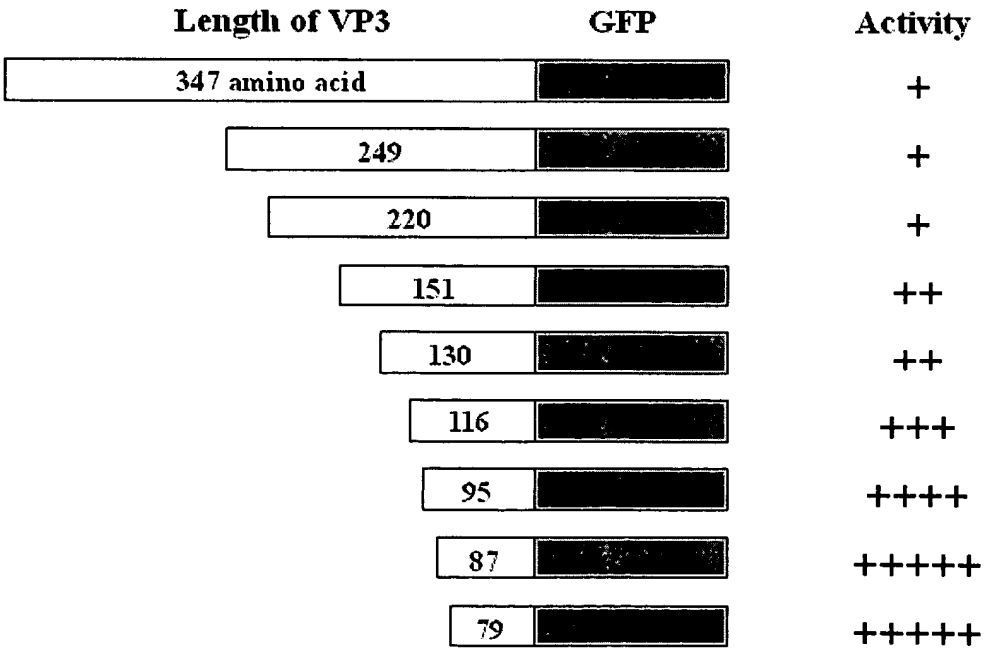
Ohta et al is an international application filed by inventors including the present inventor. Therefore, the present inventor is fully aware of the content of Ohta et al. The differences between the prior art and the present application are explained below.

In Ohta et al, to make protein embedded into a polyhedron of Cyprovirus or Cytoplasmic polyhedrosis virus, the overall length or the front half (VP3-Xba) of VP3 protein of the virus is used as an embedding signal for polyhedron. On the other hand, the present application is based

on the finding that the length of VP3 used as the embedding signal for polyhedron can be reduced to a significantly short length.

In Ohta et al, the number of amino acids of VP3 is 1057 and the number of amino acids of VP3-Xba is 441. Because protein is usually made up of 200 or several-hundred amino acids, the long embedding signal greatly affects the three-dimensional structure of the embedded protein, thus resulting in a very high possibility that, even if protein is embedded into the polyhedron, the function of the embedded protein can be lost.

As a result of reducing the number of amino acids of VP3 and splicing those amino acids to the N terminal of GFP (green fluorescent protein), by way of example, the activity of GFP was increased in reverse proportion to the number of amino acids of VP3. In bar graphs given below, the number of amino acids indicates the number of amino acids of VP3 counting from the N terminal.



Generally, when a tag for refining is introduced to developed protein, it is thought that the shorter the length of the tag, the lesser is the influence of the tag length upon the activity of the developed protein. Reducing the number of amino acids of VP3 used as the embedding signal for polyhedron is a very important discovery from the viewpoint of embedding functional proteins having various physiologic activities to the polyhedron.

Thus, even though Ohta et al discloses embedding of developed protein into polyhedron by using VP3, it includes no suggestions regarding how to ensure the activity of functional protein when the embedding signal for polyhedron, which contains so many amino acids, is used.

Also, when the third person tries to embed protein into polyhedron based on the prior art, it is impossible to easily recognize the fact that only VP3 in the region specified in the present application is able to function as the embedding signal for polyhedron in practice.

In other words, when, even in the front half (VP3-Xba) of the VP3 protein mentioned in the prior art, any other region than that specified in the present application is used as the embedding signal for polyhedron, proper activity will not be obtained. In the case of practicing the prior art, therefore, the embedding signal for polyhedron has to be searched for in a similar manner as that described in the examples of the present application.

Thus, Ohta et al does not teach or suggest "wherein the restricted region of capsid protein VP3 is a region from the 41st amino acid residue to the 79th amino acid residue," as recited in claim 1.

For at least these reasons, claim 1 patentably distinguishes over Ohta et al. Claims 2-4, depending from claim 1, also patentably distinguish over Ohta et al for at least the same reasons.

Claims 1-4 and 6-8 were rejected under 35 USC §102(a) as being anticipated by or, in the alternative, under 35 USC §103(a) as being obvious over Mori et al. (JP 2003-155300, 2003 "Mori").

Mori et al is not a 102(b) reference but a 102(a) reference. Also, an inventor of Mori et al is the present inventor. The present inventor submits herewith a "Declaration Under 37 CFR § 1.132 That Inventors Named In This Application Conceived Or Invented The Subject Matter Which Is Disclosed In The Cited Publication."

Rejections under 35 USC §103(a)

Claim 6 was rejected under 35 USC §103(a) as being obvious over Ohta (WO 02/36785) in view of Hosokawa et al. (Materials Research Society, Symposium C, Bio-inspired Nanoscale Hybrid Systems, December 2002) and Ito et al. (Appl. Physics Lett. 78:2566-2568, 2001).

Claim 6 depends from claim 1.

Hosokawa et al has been cited for allegedly disclosing a biosensor. Such disclosure of Hosokawa et al does not remedy the deficiencies of Ohta et al discussed above.

Ito et al has been cited for allegedly disclosing a method for fixing nanoparticles onto a glass substrate using a 1064 nm Nd3 : YAG Laser, wherein the nanoparticles comprise a fluorescent dye, and the nanoparticles are placed onto the glass substrate in a dot or a line. Such disclosure of Ito al does not remedy the deficiencies of Ohta et al discussed above.

For at least these reasons, claim 6 patentably distinguishes over Ohta et al, Hosokawa et al and Ito et al.

Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ohta (WO 02/36785).

Claims 7 and 8 depend from claim 1. As already discussed above, claim 1 patentably distinguishes over Ohta et al.

For at least these reasons, claims 7 and 8 patentably distinguish over Ohta et al.

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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Attachment: Declaration Under 37 CFR § 1.132